IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INGENUS PHARMACEUTICALS, LLC, Plaintiff, v. HETERO USA, INC., HETERO LABS LTD., and HETERO LABS LTD. UNIT-VI, Defendants.	C.A. No. 24-1025-JLH

PLAINTIFF'S ANSWERING BRIEF IN OPPOSITION TO HETERO'S MOTION FOR SUMMARY JUDGMENT (D.I. 69)

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I. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff Ingenus Pharmaceuticals, LLC ("Ingenus") submits this answering brief in opposition to the Motion for Summary Judgment (D.I. 69) filed by Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI ("Hetero"). Also pending and fully briefed is Ingenus's motion to stay. (D.I. 49)

II. SUMMARY OF ARGUMENT

1. The judgment from the *Nexus* Action is not "sufficiently firm" to be a "final and valid judgment" that would warrant collateral estoppel under well-established Third Circuit precedent. Hetero misstates the applicable law on multiple occasions, relying on rules from other circuits that simply are not the law here. Several factors, including the summary judgment posture of the *Nexus* opinion, the potential loss of damages to Ingenus, which filed this suit, and the pending *Nexus* Appeal, weigh against applying collateral estoppel.

2. An award of collateral estoppel is also inappropriate because Ingenus did not have a full and fair opportunity to litigate the question of indefiniteness in the *Nexus* Action.[1] The court's ruling in the *Nexus* Action made clear that it did not understand the disclosures in the specification of the '952 Patent on which its opinion was based. As a result, the court's failure to understand the complexities of the technical features of the patent ultimately foreclosed Ingenus's ability to fully and fairly litigate the issue of indefiniteness at summary judgment.

III. ANSWERING COUNTERSTATEMENT OF FACTS

1. U.S. Patent No. 10,993,952 (the "'952 Patent") is entitled "Stable ready to use cyclophosphamide liquid formulations." (attached as **Exhibit A**)

[1] Ingenus argues on appeal that the *Nexus* Court's indefiniteness finding is incorrect, but it does not make that argument here.

2. The ’952 Patent discusses stability in a number of contexts. In one embodiment, the ’952 Patent specification states that “[t]he inventors have discovered a stable ready to use, liquid parenteral formulations of Cyclophosphamide which is stable and has impurities controlled within the acceptable limits[.]” ’952 Patent, 2:41–44.

A. Claim 1 involves impurities A, B and D

3. “The impurities formed by the hydrolytic degradation of Cyclophosphamide are designated as Impurity A, B and D. These impurities are structurally identified and described in the art.” *Id.*, 2:44-47.

4. The specification defines impurity A to be “Bis(2-chloroethyl)amine hydrochloride[,]” *id.*, 2:48, impurity B to be “3-(2-Chloroethyl)-2-oxo-2-hydroxy-1,3,6,2-oxadiazaphosphonane[,]” *id.*, 2:55–56, and impurity D to be “3-[2-(2-Chloroethylamino)ethylamino] propyl dihydrogen phosphate dihydrochloride[,]” *id.*, 3:1–2.

5. The specification states: “In the first aspect of the invention, ready to use Cyclophosphamide formulations with excellent storage stability are described. The formulations of the present invention are tested for stability after being stored at 40° C., 75% RH for 7 days.” *Id.*, 3:11–15. “The formulations show less than 0.5% each of impurities A, B and D, more preferably less than 0.4% each of impurities A, B and D.” *Id.*, 3:16–18.

6. Claim 1 of the '952 Patent recites:

> **1**. A stable liquid parenteral formulation of cyclophosphamide comprising
> i) cyclophosphamide in a concentration of about 12% to about 23% based on total formulation weight;
> ii) an ethanol content of about 70% to about 75% based on total formulation weight;
> iii) both polyethylene glycol and propylene glycol, wherein a polyethylene glycol to propylene glycol mass ratio is between approximately 1.0:1.0 to approximately 2.0:1.0; and
> iv) about 3.4% to about 8.8% based on total formulation
> v) about 3.4% to about 4.4% based on total formulation weight of propylene glycol
> vi) wherein, after storage for 7 days at 40° C./75% RH, decomposition to form any of the following impurities is less than 0.5%:
> a) bis(2-chloroethyl)amine hydrochloride;
> b) 3-(2-chloroethyl)-2-oxo-2-hydroxy-1,3,6,2-oxadiazaphosphonane; and
> c) 3-[2-(2-chloroethylamino)ethyl amino] propyl dihydrogen phosphate dihydrochloride.

Id., 7:21–8:10. These impurities A, B and D as defined in Column 2 are identified by name in Claim 1. *Id.*, 8:6–10. Therefore, Claim 1 of the '952 Patent consistently recites the presence of impurities A, B and D in quantities less than 0.5% of total formulation weight. *Id.*, 8:3–10. This limitation of Claim 1 also requires these quantities of impurities to be present "after storage for 7 days at 40°C./75% RH[.]" *Id.*, 8:3. In the Nexus Action, these conditions were referred to as the "Accelerated Conditions Test." (*E.g.*, D.I. 71, Ex. 3 at 7)

B. Other impurities and storage conditions disclosed in the specification

7. The specification also discloses that "[t]he inventive compositions of Cyclophosphamide were found to be stable when stored at 2°C. to 8°C. temperature." '952 Patent, 3:17–19. In the Nexus Action, the parties referred to these conditions as the "Refrigerated Conditions." (*E.g.*, D.I. 71, Ex. 3 at 6) The '952 Patent does not claim results under these so-called

Refrigerated Conditions. '952 Patent, 7:21–8:30. As is discussed herein, the *Nexus* Court took the position that "Refrigerated Conditions" is some form of a test that is required under the claims. (D.I. 71, Ex. 3 at 10 ("each claim must also be tested under Refrigerated Conditions"))

8. The specification also discusses other impurities. For example, Table 1 of the '952 Patent is broader than Claim 1, and features stability data on impurities A, B, D, E and G.

TABLE 1

Stability data of the invention formulation

		Stability Data at 40° C./75% RH				
		Example 2		Example 4		Example 5
S. No.	Impurities	Initial	1 Week	Initial	1 Week	1 Week
		Impurities (% w/w)				
1	Impurity-A	ND	ND	0.01	0.05	ND
2	Impurity-B	0.06	0.18	0.05	0.19	0.21
3	Impurity-D	ND	ND	ND	ND	ND
4	Impurity-E	ND	ND	ND	0.45	0.65
5	Impurity-G	ND	ND	ND	1.24	1.22
6	Total	0.07	1.87	0.06	2.01	2.33
7	Assay (%)	101.6	101.9	102.1	98.9	99.7

ND: Not detectable

'952 Patent, 4:21–37 (Table 1). The '952 Patent claims do not address impurities E and G and they do not encompass examples 4 and 5 which contain those unclaimed impurities. *Id.*, 7:21–8:30.

C. The *Nexus* Court's Opinion

9. In its summary judgment ruling, the *Nexus* Court outlined two sets of issues that it was unable to reconcile in the context of the '952 Patent. The first was the scope of the impurities claimed. The second was the scope of the testing required by the claims. The *Nexus* Court concluded that "[a] POSA could not be reasonably certain under which test or what conditions the claimed formulations are stable, and thus under which test or conditions a similar invention could be said to infringe on the patent's claims." (D.I. 71, Ex. 3 at 8)

1. The *Nexus* Court interpreted the invention in the '952 Patent to encompass Table 1 and impurities E and G

10. The *Nexus* Court outlined aspects of stability discussed by the experts, including "control[ling] impurities within acceptable limits." (D.I. 71, Ex. 3 at 7 (internal quotation marks omitted)) The court did not understand the Table 1 data, particularly with respect to formulation examples 4 and 5 and impurities E and G. For example, despite the clear language of Claim 1 and the disclosures in Column 3 of the specification, the *Nexus* Court expressed confusion and stated "it is not clear to the Court whether only impurities A, B, and D must be within acceptable limits or whether all the impurities contemplated in the patent's Table 1 must be below acceptable limits." (*Id.* at 7 n.3) The *Nexus* Court added "[i]t is also not clear to the Court what those acceptable limits are, as Table 1 shows impurity G at over 1% after one week in two examples." (*Id.*) The *Nexus* Court did not consider the question of whether examples 4 and 5 were claimed in the '952 Patent.

2. The *Nexus* Court interpreted the statement about Refrigerated Conditions to be a test for stability

11. In another portion of its opinion, the *Nexus* Court concluded that "neither the patent nor its prosecution history are clear whether the 0.5% impurity threshold is relevant to evaluating stability under Refrigerated Conditions." (*Id.* at 11)

12. The Nexus Court explained that Dr. Rabinow, Ingenus's expert, "appeared to believe that, to infringe on the patent, an accused product must be stable under the Accelerated Conditions Test and under Refrigerated Conditions." (*Id.* at 8) "To the extent that Dr. Rabinow is wrong, and the claimed formulations do not need to be tested for stability under Refrigerated Conditions, then it cannot be said that a person of ordinary skill in the art can be reasonably sure of the patent's scope when that scope cannot be ascertained by Ingenus's own expert." (*Id.* at 10) But "[t]o the extent that Dr. Rabinow is correct that, contrary to the position of Ingenus's counsel, each claim must also be tested under Refrigerated Conditions, Ingenus has another problem." (*Id.*)

That problem, according to the Court, was that the specification "provides no information about what parameters that [Refrigerated Conditions] test would involve." (*Id.*)

IV. ARGUMENT

Hetero relies heavily on the *Upjohn* case, which states principles of out-of-circuit case law that *do not apply* in the Third Circuit. Under Third Circuit precedent, the *Nexus* Court's finding of indefiniteness is not "sufficiently firm" to be "a final and valid judgment" as required by the law. For example, unlike the Fourth Circuit case law discussed in *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1381 (Fed. Cir. 1999) ("Although the Fourth Circuit has not directly spoken on the issue . . ."), and cited by several courts in this district (D.I. 70 at 4, 9), courts within the Third Circuit, can—and should—consider factors such as the procedural posture of the litigation leading up to the court's judgment as well as the pending *Nexus* Appeal before the Federal Circuit. Also, in view of the *Nexus* Court's failure to grasp the technical subject matter and issues in suit, Ingenus did not have a full and fair opportunity to litigate the issue in question in the *Nexus* Action.

A. Third Circuit Legal Standards

Even though this is a patent case, Third Circuit law applies to the issue of collateral estoppel. *E.g.*, *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1359 (Fed. Cir. 2006) (citation omitted). The Third Circuit has identified four standard requirements for the application of collateral estoppel—these are whether: (1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action. *Jean Alexander Cosms, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (citations omitted). Additionally, courts consider "whether the party being precluded 'had a full and fair opportunity to litigate the issue in question in the prior action,'" *id.* (quoting

Seborowski v. Pittsburgh Press Co., 188 F.3d 163, 169 (3d Cir. 1999)) "and whether the issue was determined by a final and valid judgment," *id.* (citing *Nat'l R.R. Passenger Corp. v. Pa. Pub. Util. Comm'n*, 288 F.3d 519, 525 (3d Cir. 2002)).

B. The *Nexus* judgment is not sufficiently firm for purposes of issue preclusion

Hetero contends that the requirement that there be a "final and valid judgment" is simply ministerial and was satisfied when "the Northern District of Illinois entered final judgment of invalidity on May 9, 2025." (D.I. 70 at 6) Not so. Hetero does not identify a single case supporting "the proposition that the Court ***must*** apply issue preclusion[.]" *Glen v. Trip Advisor LLC*, 529 F. Supp. 3d 316, 326 n.8 (D. Del. 2021), *aff'd,* 2022 WL 3538221 (3d Cir. Aug. 18, 2022) (emphasis in original). Under relevant precedent, the *Nexus* judgment is not a "final and valid judgment."

"'Finality' for purposes of issue preclusion is a more 'pliant' concept than it would be in other contexts." *Dyndul v. Dyndul*, 620 F.2d 409, 412 (3d Cir. 1980) (citing Restatement (Second) of Judgments § 41). "There is no bright-line rule regarding what constitutes a 'final judgment' for issue preclusion. Instead, [the Third Circuit has] found that a prior adjudication of an issue in another action must be 'sufficiently firm' to be accorded conclusive effect.'" *Free Speech Coal., Inc. v. Attorney Gen. of U.S.*, 677 F.3d 519, 541 (3d Cir. 2012) (quoting *In re Brown*, 951 F.2d 564, 569 (3d Cir. 1991)). "Factors that courts consider when determining whether the prior determination was sufficiently firm include: 'whether the parties were fully heard, whether a reasoned opinion was filed, and whether that decision could have been, or actually was, appealed.'" *Id.* (quotation omitted). "None of these factors appears to be determinative." *Id*.

Several factors weigh against the conclusion that the *Nexus* Court's judgment is sufficiently firm to be afforded preclusive effect. First, the *Nexus* Court construed the "stable" term in the '952 Patent and found it to be indefinite at summary judgment. Indefiniteness is a question of law subject to a determination of underlying facts. *E.g.*, *Columbia Ins. Co. v. Simpson Strong-Tie Co.*

Inc., 2023 WL 2733427, at *2 (Fed. Cir. Mar. 31, 2023). In determining those underlying facts, the *Nexus* Court relied on the papers and did not hear evidence or argument. By contrast, in many patent cases where courts apply collateral estoppel, they do so after a trial on the merits with a finding of invalidity upheld after post-trial briefing: procedural facts that courts often spell out in detail. *E.g.*, *PureWick Corp. v. Sage Products, LLC*, 2023 WL 2734779 (D. Del. Mar. 31, 2023) (jury trial, verdict, and post-trial briefing); *Biogen Int'l GmbH v. Amneal Pharm. LLC*, 487 F. Supp. 3d 254, 264 (D. Del. 2020) (bench trial and post-trial briefing). The procedural posture here—summary judgment with no technology presentation by expert witnesses, no hearing, and no opportunity for reargument—weighs against the conclusion that the parties were fully heard on the question of indefiniteness.

Second, the Court's opinion expressed confusion about specific arguments and the testimony of Ingenus's expert witness, Dr. Rabinow. *Supra*, Section IIII.C. The *Nexus* Court ultimately constructed a logical proof to circumscribe its conclusion. The number of open questions the Court expressed in its opinion suggests that it had further questions for the parties that should have been explored in an evidentiary hearing and/or oral argument. The *Nexus* Court's opinion did not: recite any of the claims it invalidated, identify what qualifications and experiences a person of ordinary skill in the art would have, make factual findings on the record, or even identify which issues of material fact were undisputed. Also, the Court failed to grasp key aspects of the technology and the disclosures in the specification. These facts weigh against the conclusion that the parties were fully heard as well as the conclusion that the Court issued a reasoned opinion.

Third, Ingenus has appealed the *Nexus* judgment.[2] On appeal are questions of claim construction and the *Nexus* Court's finding of indefiniteness. Roughly 40% of appeals of district court findings of indefiniteness are reversed by the Federal Circuit—this is one of the highest rates of reversal of all types of patent rulings appealed. Janet M. Smith, *Indefiniteness as an Invalidity Case*, 58 Wm. & Mary L. Rev. 1403, 1407 (2017) (citing Ted Sichelman, *Myths of (Un)certainty at the Federal Circuit*, 43 Loy. L.A. L. Rev. 1161, 1175–76 (2010)); *see also Depomed, Inc. v. Purdue Pharma, L.P.*, Civil Action No. 13-571(MLC), 2017 U.S. Dist. LEXIS 85368 (D.N.J. June 5, 2017) (noting in dicta that "The Federal Circuit routinely reverses and remands cases on the basis of the district court's claim construction and indefiniteness opinions."). "While a prior decision may be treated as issue preclusive even when it is on appeal, doing so could 'create later problems if a first judgment, relied on in a second proceeding, is reversed on appeal.'" *Glen v. Trip Advisor*, 529 F. Supp. 3d at 326 (quoting *United States v. 5 Unlabeled Boxes*, 572 F.3d 169, 175 (3d Cir. 2009)). Therefore, this factor weighs against the application of collateral estoppel.

Fourth, these "later problems" include Ingenus's ability to collect damages for infringement for the period of time after dismissal of this case in the event Hetero launches its ANDA product prior to any Federal Circuit reversal of the *Nexus* Court's ruling. This factor also weighs against collateral estoppel. *Sound View Innovations, LLC v. Walmart Inc.*, 2019 WL 7067056, at *4 (D. Del. Dec. 23, 2019), *report and recommendation adopted,* 2020 WL 136864 (D. Del. Jan. 13, 2020) (quotation marks omitted) ("If the Court found that Sound View was

[2] Hetero wrongly (and repeatedly) argues that "[t]he law is well settled that the pendency of an appeal has no effect on the finality or binding effect of a trial court's holding." (D.I. 70 at 4 (citing *Upjohn*, 170 F.3d at 1381); *see also id.* at 9 (same)) The Third Circuit specifically allows courts to consider appeals when evaluating collateral estoppel. *Free Speech*, 677 F.3d at 541. Moreover, the *Upjohn* case applied Fourth Circuit case law of collateral estoppel, which favors the movant, whereas Third Circuit case law tends to favor the non-moving party. *Sound View Innovations, LLC v. Walmart Inc.*, 2019 WL 7067056, at *3 n.5 (D. Del. Dec. 23, 2019).

collaterally estopped from asserting these patents here and granted dismissal, but then the *Hulu* Order and/or PTAB Decisions were later overturned on appeal, the result could be that Sound View would be left without the ability to collect much or any damages . . . . In contrast, staying these actions as to these patents would maintain the status quo for Sound View's damages claim[.]"); *see also SmileDirectClub, LLC v. Candid Care Co.*, 2021 WL 3598287, at *3 (W.D. Tex. July 1, 2021) (same). These cases not only weigh against issue preclusion but also weigh in favor of staying the instant case.

Fifth, another factor Third Circuit courts consider is whether a party could have obtained review of the judgment in the initial action. *Nat'l R.R. Passenger Corp. v. Pennsylvania Pub. Util. Comm'n*, 288 F.3d 519, 525 n.3 (3d Cir. 2002) (quoting Restatement (Second) of Judgments § 28). In the *Nexus* Action, the court issued its opinion, entered final judgment, and closed the case on the same day. (D.I. 71, Ex. 3, Ex. 4) Under this timeline, there was simply no opportunity for Ingenus to request review of the judgment in the *Nexus* Action. This factor also weighs against collateral estoppel.

For the reasons stated above, the factors outlined by the Third Circuit weigh against the conclusion that the judgment in the *Nexus* Action is sufficiently firm. Therefore, the judgement is not a final and valid judgment, and collateral estoppel should not apply.

1. None of the cited cases involve a "final and valid judgment" as a matter of Third Circuit case law

The cases cited by Hetero in its "Legal Framework" and final judgment sections do not address the question of whether there is a "final and valid judgment" under Third Circuit case law. (D.I. 70 at 3–4 and 5–6) In some cases, finality was not at issue. *Biogen Int'l GmbH v. Amneal Pharm. LLC*, 487 F. Supp. 3d 254, 263 (D. Del. 2020) (noting that plaintiff did not dispute whether the four factors of the collateral estoppel analysis were met); *Galderma Labs. Inc. v. Amneal*

Pharm., LLC, 921 F. Supp. 2d 278, 280 (D. Del. 2012) ("Galderma does not challenge Amneal's contention that the issue of infringement of the Ashley patents was actually decided in the Mylan Action, and that decision (although currently on appeal) is presently embodied in a final and valid judgment."). In the *PureWick* matter, Judge Noreika, cited *Upjohn's* principles of Fourth Circuit case law in the context of staying the case but not in relation to finality. *PureWick Corp.*, 2023 WL 2734779, at *11 ("It is a far more efficient use of time and resources to allow this case to proceed on the issues of infringement and invalidity under § 112. Thus, the Court declines to stay this case."). Another case did not even explain the court's reasoning or the matters in dispute. *Wireless Discovery LLC v. eHarmony, Inc.*, 654 F. Supp. 3d 360, 367 (D. Del. 2023).

Finally, in the *Rakuten* case, Judge Williams considered the question of finality and rejected Third Circuit approaches in favor of Fourth Circuit principles. *Int'l Bus. Machines Corp. v. Rakuten, Inc.*, 2022 WL 17848779, at *8 (D. Del. Dec. 22, 2022) (quoting *Upjohn*, 170 F.3d at 1381). Although courts in Delaware have cited, and in some cases followed, the principles of these other circuits, there is no evidence that those principles state the law of what constitutes a "final and valid judgment" in the Third Circuit.

C. Full and fair opportunity

Ingenus did not have a full and fair opportunity to litigate the issue of indefiniteness, because the *Nexus* Court misinterpreted the mere mention of Refrigerated Conditions to be an affirmative test for stability. Additionally, the court did not understand which of the impurities mentioned in the '952 Patent were relevant to the invention—as a result, the court failed to grasp the nature of the claimed impurity profile as a measure of stability. Taken together, the *Nexus* Court's misapprehensions deprived Ingenus of a full and fair opportunity to litigate the validity of the '952 Patent.

A judgment of invalidity will have no collateral estoppel effect if the patentee can show that it did not have a full and fair opportunity to litigate. *Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 332–34 (1971). *Blonder-Tongue* provides a list of some, but not all, of the factors which may be considered in determining whether a patentee has had a full and fair opportunity to litigate the relevant issue or issues in a prior case including:

> whether the opinions filed by the District Court and the reviewing court, if any, indicate that the prior case was one of those relatively rare instances **where the courts wholly failed to grasp the technical subject matter and issues in suit**; and whether without fault of his own the patentee was deprived of crucial evidence or witnesses in the first litigation.

Id. at 333–34 (emphasis added) (footnote omitted). "Although there is no exhaustive list of appropriate inquiries, it is clear from the case law that has developed since *Blonder-Tongue* that an inappropriate inquiry is whether the prior finding of invalidity was correct[.]" *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 709 (Fed. Cir. 1983).

In the *Nexus* Action, the Court failed to grasp several aspects of the technical subject matter and issues in suit. Specifically, the *Nexus* Court did not appear to grasp the distinction between claimed and unclaimed subject matter in the '952 Patent.

First, the *Nexus* Court failed to grasp the disclosure and interpreted the statement about Refrigerated Conditions to describe an affirmative test for stability required by the claims, *supra,* Section III.C.2, even though recognizing "Claim 1 says nothing about refrigerated conditions[,]" (D.I. 71, Ex. 3 at 7). The '952 Patent outlines the prior art, including freeze-dried or powdered mixtures of Cyclophosphamide, and discusses that the "need to develop formulations of Cyclophosphamide overcoming the disadvantages of products and processes known in the art." '952 Patent, 1:65–67. The '952 Patent states that "[t]he inventors have discovered a stable ready to use, liquid parenteral formulations of Cyclophosphamide which is stable and has impurities

controlled within the acceptable limits. *Id.*, 2:41–44. It then identifies impurities A, B and D, which are "formed by the hydrolytic degradation of Cyclophosphamide." *Id.*, 2:44–3:10. Since Cyclophosphamide breaks down in the presence of water, the '952 Patent states that the inventors have discovered a formulation that does not degrade beyond certain levels when stored in a warm, high-humidity environment: "[i]n the first aspect of the invention, ready to use Cyclophosphamide formulations with excellent storage stability are described. The formulations of the present invention are tested for stability after being stored at 40° C., 75% RH for 7 days." *Id.*, 3:11–15.. The levels of impurities are described: "[t]he formulations show less than 0.5% each of impurities A, B and D, more preferably less than 0.4% each of impurities A, B, and D." *Id.*, 3:16–18. Claim 1 of the '952 Patent is limited to a formulation that, under the previously-described conditions, forms less than 0.5% of impurities A, B and D. *Id.*, 7:21–8:10.

The '952 Patent also states, with respect to this first aspect of the invention, that "[t]he inventive compositions of Cyclophosphamide were found to be stable when stored at 2° C. to 8° C. temperature." *Id.*, 3:19–20 ("Refrigerated Conditions"). The '952 Patent contains no other discussion of refrigeration and does not claim results associated with these conditions. This statement by the inventors reflects their conclusion that the claimed formulations remain stable under refrigeration. The patent primarily addresses what happened under the Accelerated Conditions Test and focuses on "the second aspect of the invention, ready to use formulations" comprising "Cyclophosphamide monohydrate, one or more solvents and optionally an antioxidant." *Id.*, 3:21–24; *see also id.*, 3:25–7–18.

In view of the disclosures in the '952 Patent, it is clear that the *Nexus* Court wholly failed to grasp the technical subject matter related to refrigeration, which has since become a key issue in the suit. The Court did not understand that the inventors did not disclose research into specific

aspects of stability under refrigeration, did not disclose experiments with potential compounds under refrigeration, did not disclose a test for evaluating potential compounds under such conditions, and did not claim to have invented compounds that would be tested or evaluated in such a manner.

The *Nexus* Court was clear that, based upon a single sentence mentioning refrigeration in the specification, it expected there to be detailed disclosures in the '952 Patent related to this purported test and that the absence of those disclosures made the patent invalid. (D.I. 71, Ex. 3 at 9–11); *see also supra,* Section III.C.2. Here, the court was "faced with esoteric and complex subject matter beyond its experience and comprehension," resulting in its failure to grasp the technical subject matter and issues in suit. *CollegeSource, Inc. v. AcademyOne, Inc.*, 2015 WL 5638104, at *15 (S.D. Cal. Sept. 24, 2015), *aff'd,* 709 Fed. Appx. 440 (9th Cir. 2017) (*quoting Miller Brewing Co. v. Joseph Schlitz Brewing Co*., 605 F.2d 990, 993 (7th Cir. 1979)). For these reasons, Ingenus did not have a full and fair opportunity to litigate this aspect of indefiniteness.

Second, with respect to the "second aspect of the invention," '952 Patent, 3:21, the *Nexus* Court failed to grasp exactly which formulations were tested and which specific ones were ultimately claimed in the '952 Patent. After describing the preferred embodiment of the formulation, the patent states: "Cyclophosphamide formulations prepared according to the invention were tested for stability under accelerated condition for a period of 1 week at 40° C./75% RH. The stability data of the invention formulation is summarized in table 1." *Id.*, 4:15–19.

TABLE 1

Stability data of the invention formulation

		Stability Data at 40° C./75% RH				
		Example 2		Example 4		Example 5
S. No.	Impurities	Initial	1 Week	Initial	1 Week	1 Week
		Impurities (% w/w)				
1	Impurity-A	ND	ND	0.01	0.05	ND
2	Impurity-B	0.06	0.18	0.05	0.19	0.21
3	Impurity-D	ND	ND	ND	ND	ND
4	Impurity-E	ND	ND	ND	0.45	0.65
5	Impurity-G	ND	ND	ND	1.24	1.22
6	Total	0.07	1.87	0.06	2.01	2.33
7	Assay (%)	101.6	101.9	102.1	98.9	99.7

ND: Not detectable

Id., Table 1. This table shows the presence of impurities A, B, D, E and G in examples 2, 4 and 5 under accelerated conditions testing. To be clear, although the '952 Patent specifically defines impurities A, B and D, it does not explain what impurities E and G are.[3] The patent states with respect to Table 1, "[s]urprisingly no significant increase of impurities A, B and D was observed even at accelerated conditions. The data confirms the inventors' finding that the use of suitable solvents in suitable proportions and an anti-oxidant yield best results." *Id.*, 4:38–42.

Example 2 contains cyclophosphamide, polyethylene glycol, ethanol, propylene glycol, and monothioglycerol. *Id.*, 5:5–30. These are the required components of the claimed formulation. *Id.*, 7:21–8:30. The *Nexus* Court failed to grasp that neither example 4 nor 5 contains propylene glycol, and so neither formulation is claimed. The Court's focus on impurities E and G—found only in *unclaimed* formulations—demonstrates its failure to grasp not only the difference between

[3] Consistently, the patent says repeatedly that the focus of the invention is a reduction in the formation of impurities **A, B and D**. '952 Patent, 2:1–5, 2:41–46; 3:16–19. Nowhere other than Table 1 are impurities E and G even mentioned, further demonstrating the court's inability to understand the difference between the claimed and unclaimed impurities.

the claimed and unclaimed formulations, but that the claims only recite a reduction in impurities A, B and D in formulations containing propylene glycol.

And yet, the *Nexus* Court based its invalidity determination, in part, on Table 1, including the Court's stated confusion over why impurity G is not part of the Accelerated Conditions Test. (D.I. 71, Ex. 3 at 7 & n.3 ("It is also not clear to the Court what those acceptable limits are, as Table 1 shows impurity G at over 1% after one week in two examples.")) Elsewhere, the *Nexus* Court further demonstrates that it does not grasp what Table 1 communicates by referring to "the other impurities in Table 1" as somehow relevant to the claims of the '952 Patent. (*Id.* at 14) For these additional reasons, Ingenus did not have a full and fair opportunity to litigate these aspects of indefiniteness.

Third, in a case applying this same standard under *Blonder-Tongue*, the Third Circuit outlined factors demonstrating that an earlier court *had grasped* the technical subject matter and issues in suit when it invalidated a patent for indefiniteness, stating:

> Judge Freeman, the district judge in McLouth, allocated an unusual amount of time to the trial, and devoted considerable effort to understanding the underlying industrial and scientific principles. He was alert to the contentions of the parties and "keenly aware of the issues for decision." This is evidenced by Judge Freeman's reading of voluminous documents, his presence at experiments scheduled for his edification, and his close attention to questioning at trial, all recited in his opinion. Moreover, the judge himself conducted intelligent questioning of counsel and expert witnesses during the trial and arguments.
>
> The Michigan court produced a comprehensive and comprehensible opinion, where extensive evidence was marshalled in an orderly and readily-digested fashion. A description of general steelmaking procedures was followed by a detailed discussion of the basic oxygen method. The exposition of the oxygen process revealed that the writer possessed a sure understanding of what occurred, chemically as well as physically, during the basic oxygen process. Finally, the Michigan court undertook a meticulous legal analysis of the requirements of definiteness under Section 112.

Kaiser Indus. Corp. v. Jones & Laughlin Steel Corp., 515 F.2d 964, 984 (3d Cir. 1975), *amended,* 524 F.2d 1154 (3d Cir. 1975) (footnote citations omitted). By stark contrast, the *Nexus* Court found indefiniteness, including weighing the testimony of the experts, without hearing evidence or holding oral argument. There was no lengthy trial or "presence at experiments scheduled" for the Court's edification. Instead, the *Nexus* Court issued an opinion in which it expressed confusion about the disclosures in the '952 Patent and the nature of the claimed invention. In this ruling, the *Nexus* Court laid bare its failure to grasp that the patentee had no intention to disclose, or claim, a test under refrigerated conditions. It also made clear that the *Nexus* Court did not understand that, by including Table 1 in the '952 Patent, the patentee was disclosing formulations, both claimed and unclaimed, that demonstrated a reduction in the formation of impurities A, B and D. On these bases, the *Nexus* Court's failures deprived Ingenus of a full and fair opportunity to litigate the issue of indefiniteness.

V. CONCLUSION

The *Nexus* judgment is not sufficiently firm to warrant issue preclusion. Alternatively, Ingenus was not afforded a full and fair opportunity to litigate the issue of indefiniteness. For these reasons, Hetero's motion (D.I. 69) should be denied.

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